K140146

APR 2 9 2014

Section 5 510k Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92

Date Prepared: 1/16/2014

1. **APPLICANT**

Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com

2. **SUBMITTER and CONTACT**

John P. Waters
Regulatory Compliance Officer & Official Correspondent for
Whip Mix Corporation
361 Farmington Avenue
Louisville, KY 40217

PHONE: 502-634-5357
FAX: 502-634-4512
EMAIL: jwaters@whipmix.com
DATE: 05/24/2013

3. **DEVICE NAME**

ComfortSoft® Soft Denture Liner System

4. **COMMON OR USUAL NAME AND CLASSIFICATION**

Resin, Denture, Relining, Repairing, Rebasing
Regulation Number: **872.3760**
Product Code: **EBI**
Classification: **Class II**

5. PREDICATE DEVICE COMPARISON

ComfortSoft Soft Denture Liner System is substantially equivalent to Luci-Sof (trubyte) made by Dentsply (K964040). The Indications For Use for both devices state they are intended as a long term soft liner for removable dentures and are Shore A type material. Both are of a silicone type material and use and initiator/bonder. Both require a 2mm minimum denture base thickness. Luci-Sof has passed biocompatibility testing, but information is not available in comparison to ComfortSoft Soft Denture Liner. ComforSoft Soft Denture Liner passed biocompatibility tests for MEM elution, Guinea Pig Maximization Sensitization, Intracutaneous Toxicity, Systemic Toxicity, Sub-Acute Toxicity, Ames test, Chromosomal Aberration, and In vivo Mouse Micronucleus Extract. ComfortSoft soft Denture liner also has a bond strength of at least 1MPa whereas Luci-Sof claims a 15.3 kN/m^2.

6. DEVICE DESCRIPTION

ComfortSoft® is a high pressure cured, silicone-based soft lining material for long-term use in removable dentures. ComfortSoft® is suitable for all PMMA-based dentures. Meets ISO 10139-2 and is a Shors A hardness Type A material.

It is a, translucent, non-flowing, long-term soft silicone based liner. Use to reline, rebase or line new or existing dentures. ComfortSoft® Soft Denture Liner provides a cushion between the denture and the mouth tissues to aid in reducing sore spots, and allows improved adaptation to tissue contours thereby aiding in a comfortable fit of the denture.

7. INDICATIONS FOR USE

- The ComfortSoft® Soft Denture Liner System is intended for use as a long-term soft liner for removable dentures

8. BENCH TESTING

Testing according to ISO 10139-2:2009 was completed and passed.

9. BIOCOMPATIBILITY

ComfortSoft Soft Denture Liner System passed the following biocompatibility tests; MEM elution, Guinea Pig Maximation Sensitization, Intracutaneous Toxicity, Systemic Toxicity, Sub-Acute Toxicity, Ames test, Chromosomal Aberration, and In vivo Mouse Micronucleus Extract

10. CONCLUSION

ComfortSoft® Soft Denture Liner System is substantially equivalent to Luci-Sof from Dentsply in safety and effectiveness when used in accordance with the instructions for use. Both liners are silicone liners which meet ISO 10139-2, have the same indications for use and were found to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

Whip Mix Corporation
Mr. John P. Waters
Regulatory Compliance Officer
361 Farmington Avenue
Louisville, KY 40217

Re: K140146
Trade/Device Name: ComfortSoft® Soft Denture Liner System
Regulation Number: 21 CFR 872.3760
Regulation Name: Resin, Denture, Relining, Repairing, Rebasing
Regulatory Class: II
Product Code: EBI
Dated: February 4, 2014
Received: February 4, 2014

Dear Mr. Waters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140146

Indications for Use:

The ComfortSoft® Soft Denture Liner System is intended for use as a long-term soft liner for removable dentures.

Prescription Use ____X____ **(21 CFR 801 Subpart D)**	**AND/OR**	**Over-The-Counter Use**_____ **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2014.04.29 08:34:47 -04'00'